Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Repetitive transcranial magnetic stimulation (r-TMS) in the supplementary motor area (SMA) on the symptoms of patients with obsessive-compulsive disorder

Protocol summary

Study aim
Determining the effect of repeated transcranial magnetic stimulation in the supplementary motor area on the symptoms of obsessive-compulsive disorder patients referred to Shahid Beheshti Hospital, Kerman.

Design
randomized double-blind study, with parallel groups and with 40 patients

Settings and conduct
During 4 weeks, treatment with magnetic stimulation of the brain with Standard Rapid2 rTMS device (Magstim company) as follows: Inhibitory right and left SMA in one session (1500 pulses for each side), Orientation 180 degrees • 12 sessions, 3 times a week • Sham coil group, tilted • Both groups have drug treatment.

Participants/Inclusion and exclusion criteria
The statistical population of this research is all people with a definite diagnosis of OCD referring to Shahid Beheshti hospital clinic.

Intervention groups
OCD patients will be randomly divided into two intervention groups (Medical therapy + RTMS) and control group (Medical therapy).

Main outcome variables
Duration of infection and type of obsession (contamination, symmetry, aggression, religious and sexual, morbid doubt) and clinical symptoms - severity of obsessive-compulsive disorder - quality of life - depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230508058129N1**
Registration date: **2023-05-12, 1402/02/22**
Registration timing: **prospective**

Last update: **2023-05-12, 1402/02/22**
Update count: **0**

Registration date
2023-05-12, 1402/02/22

Registrant information

Name
Farzane Fadaie Kermani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-15, 1402/02/25

Expected recruitment end date
2023-09-23, 1402/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Repetitive transcranial magnetic stimulation (r-TMS) in the supplementary motor area (SMA) on the symptoms of patients with obsessive-compulsive disorder

Public title

The effect of Repetitive transcranial magnetic stimulation (r-TMS) in the supplementary motor area (SMA) on the symptoms of patients with obsessive-compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of OCD based on the DSM V diagnostic criteria by two psychiatrists (clinical interview) obtaining a score equal to or greater than 16 from the Y-BOCS questionnaire, not taking related drugs in the last four weeks and starting drug treatment with sertraline 150 mg (simultaneously to along with r-TMS for the intervention group), not receiving ECT in the past 6 months and the willingness of the subjects to participate in the research

Exclusion criteria:

Existence of accompanying psychiatric disorder, especially depression (based on Beck Depression Scale) score of Beck Questionnaire above 10, suffering from seizures use of drugs and substances, presence of metal implants, pacemaker, trauma or head injury and neurosurgery procedures incompleteness of patients data more than 10%

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method is available sampling method from eligible patients. Sampling will be done until reaching the desired sample size, and then the patients will be entered into two intervention and control groups based on replacement blocks. Random assignment of patients to two groups is done by permuted block stratified randomization method. In this way, first, eligible referring patients are classified according to age and gender in the order of arrival. Then they are assigned to the desired group based on blocks of 4 (consisting of two groups A and B and two repetitions for each) randomly selected from among all the possible states of permutations. These blocks were created using statistical software R version 4.0.2.

Blinding (investigator's opinion)

Double blinded

Blinding description

Grouping of patients will be done based on random sampling and in 2 groups A and B. Both groups will be exposed to similar interventions; with the difference that the control group will only be subjected to the standard drug regimen and Sham will be used for them; So that the device will be placed on the patient's scalp without magnetic stimulation. The patients and the statistical analyst were not aware of the treatment method in detail and only knew of their group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Afzalipour Hospital-Kerman University of Medical Scineces

Street address

Kerman, the beginning of Haft Bagh Alavi axis, University of Medical Sciences campus

City

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Province

Kerman

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7616913555

Approval date

2022-11-07, 1401/08/16

Ethics committee reference number

IR.KMU.REC.1401.315

Health conditions studied

1

Description of health condition studied

Obsessive-compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Yale-Brown Obsession Scale

Timepoint

Before the start of the study, after each RTMS session, 3 months after the last session

Method of measurement

Using a standard questionnaire

Secondary outcomes

1

Description
Quality of Life Brief Version (WHOQOL-BREF)
Timepoint
Before the intervention, after each session, 3 months after the last session
Method of measurement
Based on a standard questionnaire

2

Description
Symptoms of obsession
Timepoint
Before the intervention, after each session, 3 months after the last session
Method of measurement
Based on a standard questionnaire

3

Description
Beck depression questionnaire 2
Timepoint
Before the intervention, after each session, 3 months after the last session
Method of measurement
Based on a standard questionnaire

Intervention groups

1

Description
Intervention group: standard drug treatment + treatment using magnetic stimulation of the brain with rTMS device - during 4 weeks treated with magnetic stimulation of the brain with rTMS device model Standard Rapid2 (Magstim company) is as follows: Right and left SMA inhibition in one Session (1500 pulses for each side), Orientation 180 degree, 12 sessions 3 times a week + standard drug treatment which is sertraline.
Category
Treatment - Devices

2

Description
Control group: only standard medical treatment of the disease - this group will not be subjected to rTMS intervention and the device will be placed on their scalp without magnetic stimulation + standard medical treatment which is sertraline.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital Clinic, Kerman
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Farzane Fadaie Kermani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
Start access when the article is published

To whom data/document is available
It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The researcher will be available for further analysis and review studies upon request to ensure the accuracy of the data.

From where data/document is obtainable
Researcher responsible for the project - email address: pdivsalar@yahoo.com, contact number: +98 34 1211 6328, postal address: 7618834115

What processes are involved for a request to access data/document
In case of contacting the researcher responsible for the project and confirming the identity of the people, the data will be provided to them within 1 week.

Comments